



1-AF 3739

PATENT

Applicant: Fleischman et al. #188

Serial No.: 08/529,354

Filing Date: September 18, 1995

Title: Systems and Methods for
Electronically Altering the Energy Emitting
Characteristics of an Electrode Array to
Create Different Lesion Patterns
in Body Tissue

Group Art Unit: 3739

Examiner: D. Shay

2002

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Washington, DC 20231.

Craig A. Slavin

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Commissioner for Patents
Washington, D.C. 20231

**Attention: Board of Patent Appeals
and Interferences**

TRANSMITTAL OF APPEAL BRIEF

Further to the Notice of Appeal filed August 8, 2001, transmitted herewith in triplicate is the Appeal Brief, time for filing of which has been extended by the petition filed December 19, 2001 to January 8, 2002. Pursuant to 37 C.F.R. § 1.17(c), enclosed is a check in the amount of \$320 to cover the filing fee for the Appeal Brief.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

12/20/01
Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Commissioner for Patents
Washington, D.C. 20231

Attention: Board of Patent Appeals
and Interferences

APPEAL BRIEF

I. REAL PARTY IN INTEREST

01/28/2002 LFULTON 00 The real party in interest in the present appeal is EP Technologies, Inc., the
01-FC:117 assignee of the present application. EP Technologies, Inc. is a wholly owned subsidiary
of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect, or be
directly affected by, or have a bearing on, the Board's decision in the present appeal.

Adjustment date: 03/22/2002 EKUBAY1
01/09/2002 LFULTON 00000013 000638 08529354
01 FC:117 920.00 CR

01/10/2002 GTEFFERA 00000049 08529354

01 FC:120 320.00 OP

III. STATUS OF THE CLAIMS

Claims 1-27, 29, 31, 34, 37, 41 and 42 have been canceled.

Claims 28, 30, 32, 33, 35, 36, 38-40 and 43-46 are pending and are set forth in the Appendix (Exhibit 1).

Claims 28, 30, 32, 33, 35, 36, 38, 39 and 43-46 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Eggers '443 and Desai '198 patents.

Claim 40 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Eggers '443, Desai '198 and Fogarty '769 patents.

No claims have been allowed.

Applicant appeals the rejection of claims 28, 30, 32, 33, 35, 36, 38-40 and 43-46.

IV. STATUS OF THE AMENDMENTS

Applicant filed an amendment on December 19, 2001 in response to the Final Office Action dated May 10, 2001. Although applicant has not yet received an Advisory Action in response to the December 19, 2001 amendment, given that the amendment merely cancels claims 13, 16, 17, 19, 20, 41 and 42 in order to reduce the number of issues for appeal, applicant presumes that the amendment will be entered.

V. SUMMARY OF THE INVENTIONS

A. Background and Brief Description of an Exemplary Embodiment

The present inventions, as defined by the claims, are directed generally to devices that may be used in therapeutic procedures to ablate tissue. Such procedures include the treatment of cardiac rhythm disturbances. Conventional systems have, for example, been used in "maze procedures" to create a patterns of long continuous

lesions that cure atrial fibrillation. Some lesions in the pattern will, of course, be longer than others. Prior to the inventions disclosed in the present application, long continuous lesions were frequently formed with guide elements that included a distal tip electrode by dragging the tip electrode over the tissue as power was supplied to the electrode. The length of the lesion was, therefore, determined by the distance that the tip electrode was dragged over the tissue. Forming lesions in this manner was not only difficult and slow, but it also often resulted in tissue charring and (unwanted) discontinuities in the lesions.

The present inventions solve this problem by providing systems that allow lesions of varying length to be formed without dragging an electrode over the tissue. As illustrated in Figure 59 (formal version), an exemplary system 298 includes a probe 180, a plurality of conductive regions E1 to E7 on the distal portion of the probe, and a controller 300 that may be used to regulate the flow of energy from an energy source 296 to the conductive regions. The exemplary controller 300 also includes an input panel 302 with a plurality of manually operable switches that are respectively associated with the conductive regions E1 to E7. Each switch can be used to selectively block transmission of energy from the energy source 296 to the associated one of the conductive regions E1 to E7.

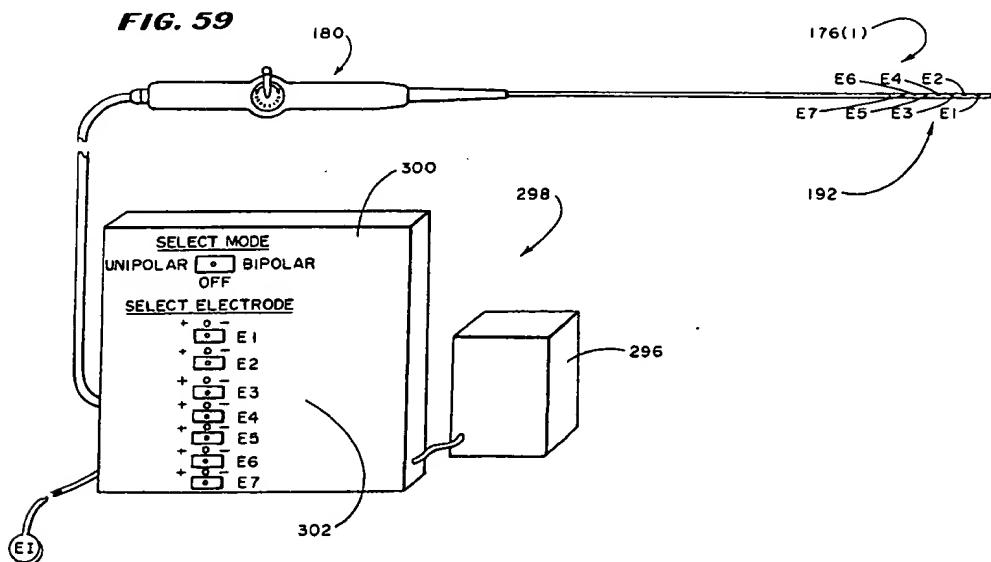


Figure 59 of the Present Application (Formal Version)

As illustrated in Figure 60 (formal version) and described on page 56, line 18 to page 59, line 19 of the specification, the exemplary input panel 302 includes an ON/OFF/MODE toggle switch T_M that allows the user turn the controller on and off and, if on, to select one of the unipolar and bipolar ablation modes. Toggles T_{E1} to $E7$, on the other hand, are used for **INDIVIDUAL ELECTRODE CONTROL**. The toggles T_{E1} to $E7$ are individually coupled to the switches S_{E1} to $E7$, which are connected to the conductive regions $E1$ to $E7$ by wires W_1 to W_7 . The S_{E1} to $E7$ regulate the flow of power to the respective conductive regions $E1$ to $E7$. As such, the toggle T_{E1-E7} can be manipulated by the user to selectively block transmission to some or all of the conductive regions $E1$ to $E7$.

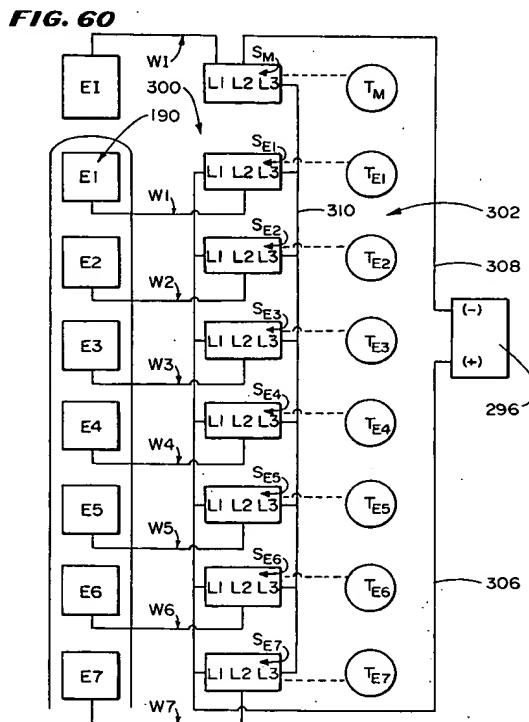


Figure 60 of the Present Application (Formal Version)

Once the distal portion of the probe 180 is in contact with tissue, the physician may use the toggles T_{E1} to $E7$ on the controller 300 to allow energy to flow to only those conductive regions $E1$ to $E7$ that will create the desired lesion. The controller may operate in, for example, one mode where a relatively short lesion is formed by only

allowing energy to flow to two conductive regions (e.g. E1 and E2), or another mode where a relatively long lesion is formed by allowing energy to flow to six conductive regions (e.g. E1 to E6), or another mode where a lesion with gaps is formed by allowing energy to flow to two spaced groups of conductive regions (e.g. E1 and E2 as well as E5 and E6).

B. Brief Description of the Invention Claimed

The present application includes two independent claims – claims 28 and 33. Dependent claims 30, 32, 43, and 44 depend from independent claim 28. Dependent claims 35, 36, 38, 39, 40, 45 and 46 depend from independent claim 33.

Independent claim 28 is directed to a system for ablating tissue within a body. The system comprises a guide element, a plurality of longitudinally spaced electrodes on the guide element, and a controller that is operably connected to the plurality of electrodes and to a source of tissue ablating energy. The controller includes an operator interface and switching means for selectively disconnecting at least one of the electrodes within the plurality of longitudinally spaced electrodes from the source of tissue ablating energy in response to a first predetermined input command such that two electrodes are electrically connected to the source of tissue ablating energy and the at least one disconnected electrode is between the two connected electrodes.

In addition to the elements set forth in independent claim 28, the combination defined by dependent claim 43 requires that the operator interface include a plurality of manually operable switches respectively associated with the plurality of electrodes.

In addition to the elements set forth in independent claim 28, the combination defined by dependent claim 44 requires that the operator interface include a plurality of manually operable on-off switches respectively associated with the plurality of electrodes.

Independent claim 33 is directed to a system for ablating tissue within a body. The system comprises a guide element, at least first, second and third contiguous

electrodes carried by the guide element arranged such that the second electrode is located between the first and third electrodes, a control device, and an indifferent electrode adapted to be located on a patient. The control device includes an operator interface that receives at least first and second predetermined input commands and is operable in a first mode in response to the first input command to simultaneously electronically couple the first, second and third electrodes to a source of tissue ablation energy such that the first, second and third electrodes simultaneously transmit ablation energy. The control device is also operable in a second mode in response to the second input command to block transmission from one of the first, second and third electrodes while simultaneously electronically coupling the other of the first, second and third electrodes to a source of tissue ablation energy such that the other of the first, second and third electrodes simultaneously transmit ablation energy.

In addition to the elements set forth in independent claim 33, the combination defined by dependent claim 45 requires that the operator interface include a plurality of manually operable switches respectively associated with the plurality of electrodes.

In addition to the elements set forth in independent claim 33, the combination defined by dependent claim 46 requires that the operator interface include a plurality of manually operable on-off switches respectively associated with the plurality of electrodes.

VI. ISSUES

The present appeal presents the following two issues:

(1) whether, in accordance with 35 U.S.C. § 103, claims 28, 30, 32, 33, 35, 36, 38, 39 and 43-46 have been properly rejected as being unpatentable over the combined teachings of the Eggers '443 and Desai '198 patents; and

(2) whether, in accordance with 35 U.S.C. § 103, claim 40 has been properly rejected as being unpatentable over the combined teachings of the Eggers '443, Desai '198 and Fogarty '769 patents.

VII. GROUPING OF THE CLAIMS

Applicant respectfully submits that claims 28, 30, 32, 43 and 44 are patentably distinct from claims 33, 35, 36, 38, 39, 40, 45 and 46, that claims 43 and 44 are patentable distinct from claims 28, 30 and 32, and that claims 45 and 46 are patentably distinct from claims 33, 35, 36, 38, 39 and 40. Accordingly, claims 28, 30 and 32 stand or fall together, claims 33, 35, 36, 38, 39 and 40 stand or fall together, claims 43 and 44 stand or fall together, and claims 45 and 46 stand or fall together.

VIII. ARGUMENTS

A. THE EGGERS PATENT

The Eggers patent is directed to a system that may be used to selectively heat atheromatous (or stenotic) material within a blood vessel while limiting the amount of heat applied to blood and the blood vessel wall. [Column 4, lines 49-54.] As illustrated in Figures 1 and 2 on the following page, the system includes a catheter 10 with an array of isolated electrodes 18 disposed on the catheter tip 12. The electrodes 18 are connected to a power source 32 that includes an operator interface with a voltage control knob 34, a temperature control knob 36, and what appears to be a **single** on-off switch that enables/disables power to **all** of the electrodes. The catheter tip 12 is provided with temperature sensors 48. The temperature sensors 48 are not specifically associated with any particular electrodes 18. Rather, a few temperature sensors 48 are packed in with mass of electrodes 18. Alternatively, each electrode may function as a thermocouple so that the maximum temperature on the tip 12 may be determined. [Column 11, lines 43-54.]

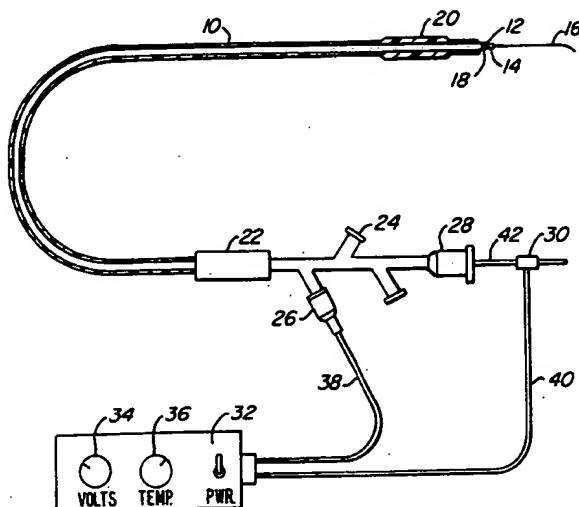


FIG. 1.

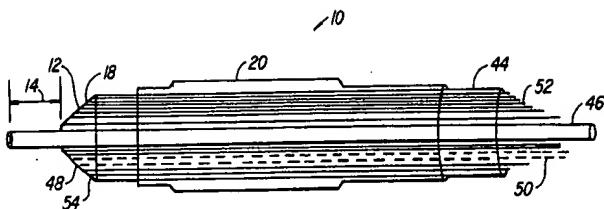


FIG. 2.

Figures 1 and 2 of the Eggers Patent

With respect to operation of the Eggers system during a recanalizing procedure, and referring to Figure 5, the Eggers tip 12 and electrodes 18 are brought into contact with the atheromatous plaque 58 in a blood vessel. Power from the power source 32 is then supplied to the electrodes 18 to heat the atheromatous plaque 58 in zone 64 in order to soften the plaque. This allows the tip 12 to be advanced through the atheromatous plaque 58 to create an opening in the blood vessel.

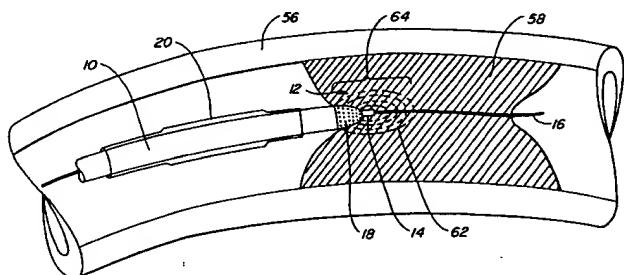


FIG. 5.

Figure 5 of the Eggers Patent

The power source 32 performs two functions during the recanalizing procedure that were identified by the Examiner at various times during the prosecution as being

relevant to the present inventions. The first function is determining whether a particular electrode 18 is transmitting power to atheromatous material (which is desirable) or is transmitting power to blood or a blood vessel wall (which is undesirable). Transmission is automatically blocked to those electrodes which are transmitting power to the blood or blood vessel wall. The second function, which is applicable only to the electrodes 18 that are transmitting power, is maintaining the temperature at the tip 12 at or below a maximum temperature set by the user. Each of these functions is discussed in greater detail below.

With respect to the first function, and referring to column 3, lines 18-28 and column 6, line 57 to column 7, line 17, the Eggers power source 32 measures resistance to individually determine whether an electrode 18 is transmitting power to atheromatous material (high resistance) or to blood or a blood vessel wall (low resistance). The Eggers power source 32 **automatically** blocks power to the electrodes 18 that are transmitting power through blood or a blood vessel wall, which allows the catheter to be "self-guiding." [Column 9, lines 18-29.] In contrast to the present inventions, the user does not play any role whatsoever in determining whether or not a particular electrode 18 receives power.

With respect to the second function, i.e. temperature control, the Eggers power source 32 allows the user to set the highest allowable tissue temperature with a single control knob 36 that is used for all of the electrodes 18. The Eggers patent specifically describes the control scheme that is employed when the temperature sensors 48 are used to sense the tip temperature.

The temperature sensors 48 at the tip 12 of the catheter 10 are connected to a feedback control system in power source 32 to adjust the power output so that the user selectable temperature is not exceeded during the use of the catheter in recanalization of an occluded blood vessel. Power output could be controlled by any conventional technique, such as control of voltage, current, duty cycle, or the like. [Column 7, lines 58-66.]

The temperature information may also "be used in the feedback control loop as described above to assure an improved safe upper limit on the operating temperature" in those instances where each electrode 18 functions as a thermocouple and the maximum temperature at the tip 12 is determined. [Column 11, lines 50-54.] In contrast

to the present inventions, however, nothing in the Eggers patent even remotely suggests that “voltage, current, duty cycle, or the like” are controlled on an electrode-by-electrode basis, let alone that the user can select which of the electrodes 18 will be controlled during the temperature control process. Nor does the Eggers patent even remotely suggest that power will be cut off to some of the electrodes 18, but not others, by the temperature control system.

B. THE DESAI PATENT

The Desai patent is directed to an ablation system 10 including “three functioning units, namely a mapping unit 20, an ablation unit 30 and a pacing unit 40.” [Figure 1 and column 5, lines 59-60.] A computer 50 with an interface 54 may be used to control the operation of each of the units. [Id.] A catheter 70, which includes electrodes 111-115, is connected to the ablation system 10 (i.e. the mapping unit 20, ablation unit 30 and pacing unit 40) by a multiplexer 80. The multiplexer 80 also connects auxiliary catheters 90 and surface electrodes 92 to the ablation system 10.

The power unit 30 is preferably “programmable and under the control of [a] computer 50, so that a predetermined amount of electrical energy is delivered to ablate the endocardium.” [Column 13, lines 56-60.] The power unit 30 may also be operated manually. [Column 6, line 63 to column 7, line 6.] There is, however, nothing in the Desai patent that even remotely suggests individual control of the electrodes 111-115 in the manner defined by the present claims.

C. CLAIMS 28, 30 AND 32

Independent claim 28 calls for a combination of elements including, *inter alia*, “a plurality of longitudinally spaced electrodes,” “an operator interface operable during an ablation procedure that receives at least a first predetermined input command,” and “switching **means** for **selectively disconnecting at least one of the electrodes** within

the plurality of longitudinally spaced electrodes from the source of tissue ablating energy *in response to the first predetermined input command* such that *two electrodes are electrically connected* to the source of tissue ablating energy and the at least one *disconnected electrode is between the two connected electrodes.*"

The cited references fail to teach or suggest such a combination. For example, and as described in detail below, the Eggers power source 32 does not selectively disconnect power to one electrode during an ablation procedure that is between two other electrodes which are connected in response to a command input into the operator interface. The Desai patent fails to remedy this deficiency.

1. The Eggers Power Blocking Function

The Eggers power source 32 *automatically* blocks power to the electrodes 18 that are transmitting power through a relatively low resistance path. As such, this aspect of the Eggers power source 32 is not performing the function of "selectively disconnecting at least one of the electrodes within the plurality of longitudinally spaced electrodes from the source of tissue ablating energy in response to [a] first predetermined input command" from a user interface. Nor is there anything in the Eggers patent that would even remotely suggest to one of ordinary skill that the Eggers power blocking function should be performed manually by the user or that power to a particular electrode (i.e. one between two that are transmitting power) should be blocked.

2. The Eggers Temperature Control Function

The Eggers power source 32 also varies the power output to the electrodes in order to prevent the tissue temperature from surpassing the temperature input by the user with the temperature control knob 36. The Eggers patent states that "[p]ower output could be controlled by any conventional technique, such as control of voltage, current, duty cycle, or the like." [Column 7, lines 63-66.] There are a variety of differences between

the temperature control function described in the Eggers patent and the function of "selectively disconnecting at least one of the electrodes ... in response to the first predetermined input command such that two electrodes are electrically connected to the source of tissue ablating energy and the at least one disconnected electrode is between the two connected electrodes" recited in the combination defined by claim 28.

For example, the Eggers patent does not even remotely suggest that power output is varied on an electrode-by-electrode basis for temperature control purposes. The Examiner apparently recognized this and, in response, has simply asserted without any foundation whatsoever that it would have been obvious to do so. [Advisory Action at page 5.] This statement, which is respectively traversed,¹ entirely ignores the fact that the Eggers patent specifically states that temperature is controlled based on "the **highest temperature** at the tip 12 of the catheter 10 during its use." [Column 7, lines 45-49.] The highest temperature will be measured by the temperature sensor 48 which happens to be in contact with hottest one of the areas being contacted by the individual sensors. Alternatively, the electrodes 18 may be used to sense temperature because the "**maximum temperature**" may occur "at any location on the tip." [Column 11, lines 42-50.] The only conclusion that one of ordinary skill in the art would draw from what the Eggers patent actually discloses is that all of the Eggers electrodes 18 (that are transmitting power) are controlled based on the **same** highest temperature reading no matter how the highest temperature is determined. Accordingly, the "voltage, current, duty cycle, or the like" would be controlled globally by the power source 32, not on an electrode-by-electrode basis, and nothing in the Eggers patent suggests otherwise.

¹ To the extent that this statement was intended to convey that the Examiner has taken "judicial notice" with respect to knowledge generally available in the art, applicant hereby traverses and requests that the Examiner provide an affidavit in accordance with MPEP § 2144.03 and 37 C.F.R. § 1.104(d)(2) to that effect. The affidavit should set forth the facts upon which the Examiner's conclusions regarding the knowledge available in the art are based. Otherwise, applicant respectfully requests that the Examiner provide a prior art reference which shows that the claimed invention would have been obvious.

Another difference between the temperature control function described in the Eggers patent and the above-quoted function from the claimed combination is that the Eggers power source 32 does not disconnect any of the electrodes to control temperature. The Examiner has apparently taken the position that varying the duty cycle of the power supplied to the electrodes 18 is tantamount to “*disconnecting* ... [an] electrode ... from the source of tissue ablating energy,” as this phrase is used in claim 28. [Advisory Action at page 5, last two sentences.] Applicant respectfully submits that the Examiner’s interpretations of the phrase “duty cycle,” its use in the Eggers patent, and the term “disconnecting” are each incorrect.²

As known to those of skill in the art, the phrase “duty cycle” is used in electrophysiology to describe one attribute of an energy waveform. A waveform with a small duty cycle, for example, has a longer time period between each pulse than a waveform with a large duty cycle.³ The Eggers patent discusses duty cycle in the context of controlling “high frequency” power to maintain temperature below the level set by the user during an *ongoing* recanalizing procedure. [Note that the Eggers patent states in column 7, lines 59-63 that the control system “*adjusts* the power output so the user selectable temperature is not exceeded *during* the use of the catheter in a *recanalization*.] The electrodes 18 are, of course, connected to the energy source because the procedure is ongoing. As such, one of skill in the art would clearly understand that when the Eggers power source 32 “controls duty cycle” of the power supplied to the electrodes 18 to control temperature, the power source is simply adjusting the time period between each pulse to maintain temperature below the set level. Turning to the present application, the word “disconnecting” is used to describe a situation where a source of tissue ablating energy is *not connected* to an electrode because, for

² “Claims in an application are to be given their broadest reasonable interpretation *consistent with the specification* [and] claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Young and Sneed*, 218 USPQ 384, 388 (Fed. Cir. 1983) [Emphasis added.]

³ See, for example, Figures 15 and 16 and column 11, lines 45-51 of U.S. Pat. No. Re. 33,925, which is attached hereto as Exhibit 2.

example, the associated switch is open. One of skill in the art would certainly understand that this entirely different than varying the time period between energy pulses when electrodes are connected to the energy source.

Yet another difference is that the Eggers power source 32 does not vary the power supplied to the electrodes 18 for temperature control purposes *in response to* a command input by the user via an operator interface. Although the Eggers system allows the user to select the maximum temperature with the knob 36, power is adjusted in response to a measured temperature. Even if the knob 36 were rotated during a recanalization procedure, the power would not be adjusted until the power source determined (1) the relationship between the measured temperature and the input temperature and (2) that this relationship *actually necessitated* a change in the output power. As such, one of skill in the art would understand that the Eggers system varies power *in response to* a measured temperature, not an input command.

Still another difference is associated with the fact that the functional statement of the means-plus-function element in the claimed combination calls for "*selectively disconnecting* at least one of the electrodes" and specifies that "*the at least one disconnected electrode is between the two connected electrodes.*" Even assuming *arguendo* that Eggers electrodes could be disconnected on an electrode-by-electrode basis for temperature control purposes, and that this occurred in response to a user input command, there is simply no way for the user to *selectively disconnect* an electrode *between* two electrodes that are connected.⁴ The user does not have any choice in the matter. There is one input maximum temperature for all of the electrodes and power would be adjusted (given these unsupported assumptions) to the electrode associated with the hot spot. Nor would there have been any reason for a skilled artisan to modify the Eggers power source 32 such that it functioned in the manner claimed, even with all of these unsupported assumptions, because power is adjusted based on

⁴ "The corresponding structure to a function set forth in a means-plus-function limitation must actually perform the recited function, not merely enable the pertinent structure to

the temperature sensed at the catheter tip 12 and the user would not have any way of knowing in advance which of the electrodes would be associated with a hot spot generally, let alone a hot spot that was between two electrodes that didn't require adjustment.

3. The Teachings of the Desai Patent

The Desai patent has been cited for its purported teaching of manually operable switches that control individual electrodes. The fact that independent claim 28 does not require such switches notwithstanding, applicant respectfully submits that the Desai patent **does not** teach or suggest manually operable switches that control individual electrodes. To the contrary, the Desai patent merely teaches that the power supplying ablation unit 30 can be operated manually (without any reference to individual electrode control) and that the multiplexer connections between the ablation system 10 (i.e. the mapping unit 20, ablation unit 30 and pacing unit 40) and the catheter 70, auxiliary catheters 90 and surface electrodes 92 can be changed manually (again without any reference to individual electrode control). As such, the Desai patent would not have suggested any modifications to the Eggers system that would have led a skilled artisan to the combination defined by independent claim 28.

4. Conclusion

As the Eggers and Desai patents fail to teach or suggest the combination of elements recited in independent claim 28, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 28, 30 and 32 under 35 U.S.C. § 103 is improper and should be reversed.

operate as intended." *Asyst Technologies Inc. v. Empak Inc.*, 60 USPQ2d 1567, 1672-73 (Fed. Cir. 2001).

D. CLAIMS 33, 35, 36 AND 38-40

In accordance with the separate patentability requirements of 37 C.F.R. § 1.192(c)(7), applicant respectfully submits that independent claim 33 (and dependent claims 35, 36 and 38-40) are novel in view of independent claim 28 (and dependent claims 30, 32, 43 and 44) for a variety of reasons. For example, independent claim 33 is novel by definition because claim 33 does not include a means-plus-function limitation, as does independent claim 28. Independent claim 28 also requires that the "at least one disconnected electrode is ***between*** the two connected electrodes." Independent claim 33 has no such requirement. In addition to being novel, applicant respectfully submits that independent claim 33 (and dependent claims 35, 36 and 38-40) are non-obvious over independent claim 28 (and dependent claims 30, 32, 43 and 44) because the prior art does not suggest modifying the invention defined by claim 33 such that "at least one disconnected electrode is ***between*** the two connected electrodes."

Turning to the rejection under 35 U.S.C. § 103, independent claim 33 calls for a combination of elements including, *inter alia*, "at least first, second and third contiguous electrodes" and "a control device, including an operator interface that receives at least first and second predetermined input commands, ***operable in a first mode in response to the first input command to simultaneously electronically couple the first, second and third electrodes to a source of tissue ablation energy*** such that the first, second and third electrodes simultaneously transmit ablation energy, and ***operable in a second mode in response to the second input command to block transmission from one*** of the first, second and third electrodes ***while simultaneously electronically coupling the other*** of the first, second and third ***electrodes to a source of tissue ablation energy*** such that the other of the first, second and third electrodes simultaneously transmit ablation energy."

The cited references fail to teach or suggest such a combination. For example, and as described in detail below, the Eggers power source 32 does not operate in first

and second modes based on commands input into an operator interface. Nor does it block transmission of tissue ablation energy from one electrode, while coupling others to an energy source, in response to a command input into an operator interface. The Desai patent fails to remedy this deficiency.

1. The Eggers Power Blocking Function

The Eggers power source 32 blocks energy transmission from some of the electrodes 18 (i.e. those transmitting power to blood or a blood vessel wall), while allowing transmission from others (those transmitting power to plaque). In contrast to the invention defined by independent claim 33, however, the Eggers power source 32 includes a **single** on-off switch for all of the electrodes 18 and energy transmission from an individual electrode is blocked **automatically**. [Figure 1 and column 7, lines 1-17.] As such, the Eggers power source does not simultaneously couple three electrodes to a source of ablation energy in response to a first input command and, in response to a second input command, block energy transmission from one of the electrodes while simultaneously coupling the other two to a source of ablation energy. The Eggers patent also fails to teach anything that would even remotely suggest to one of ordinary skill that transmission from one of the Eggers electrodes should be blocked, while two others continue to transmit power, **in response to a command** input via a user interface.

2. The Eggers Temperature Control Function

A **single** temperature control knob 36 allows the user of the Eggers system to set the maximum temperature that will be allowed at the tip 12. Temperature is measured, either by the temperature sensors 48 or by the electrodes 18, so that the maximum temperature at the tip may be determined. If necessary, the Eggers power source 32 will adjust the power output to the electrodes 18 in order to prevent the maximum

temperature at the tip 12 from surpassing the temperature input with the control knob 36. Power is adjusted by controlling the "voltage, current, duty cycle, or the like." [Column 7, lines 52-68 and column 11, lines 42-54.] There are a variety of differences between this aspect of the Eggers system and the invention defined by independent claim 33.

For example, the invention defined by independent claim 33 operates in first and second modes in response to first and second input commands. This allows the user to **specifically dictate** that, in one instance all three electrode will transmit energy and, in another instance, power will be blocked to one electrode while the other two transmit power no matter what the conditions are within the patient. The Eggers power source 32 operates in one mode – power is automatically blocked to those electrodes that are in contact with blood or a blood vessel wall (Section VIII-D-1, page 17) and, with respect to those electrodes that are transmitting energy, power is controlled based on the maximum temperature measured at the tip 12. There is no other mode of operation. No matter how the user sets the temperature control knob 36, the Eggers power source 32 operates the same way – power is blocked to those electrodes 18 that are in contact with blood or a blood vessel wall and the maximum temperature measured at the tip 12 is used to control power to those electrodes which are transmitting power.

Another difference between the invention defined by independent claim 33 and the temperature control aspect of the Eggers system is that the Eggers power source 32 does not block transmission from a particular electrodes as part of the power control process. Instead, the "voltage, current, duty cycle, or the like" to **all** of the electrodes 18 controlled **globally** by the power source 32 in response to the highest temperature detected with the sensors 48 or the electrode themselves. [This aspect of the Eggers system is discussed in greater detail in Section VIII-C-2 on page 12.]

Yet another difference between the Eggers system and the combination defined by claim 33 is that the Eggers power source 32 does not **block** transmission to any of the electrodes 18 to control temperature. The Examiner has apparently taken the position that varying the duty cycle of the power supplied to the electrodes 18 is tantamount to blocking transmission. Applicant respectfully submits that varying the duty

cycle during an ongoing procedure is not blocking transmission for the reasons discussed at length in Section VIII-C-2 on pages 13 and 14.

Still another difference between the invention defined by independent claim 33 and the temperature control aspect of the Eggers system is that the Eggers power source 32 does not switch from a condition where three electrodes 18 are coupled to an energy source and are transmitting energy, to a condition where transmission from one of the electrodes is blocked while the other two electrodes are coupled to the source and are transmitting energy, *in response to* commands that are received by an operator interface. The fact that power is not blocked for temperature control purposes notwithstanding, the Eggers power source 32 does not even adjust power output in response to commands that are input by the user. Instead, power is only adjusted *in response* to a situation where the relationship between the maximum measured temperature and the temperature input with the control knob 36 necessitates that the power be adjusted. Clearly, if the user turned the temperature knob 36 down to a new value and the measured temperature at the tip 12 was well below the new value, nothing would happen.

3. The Teachings of the Desai Patent

The Desai patent has been cited for its purported teaching of manually operable switches that control individual electrodes. The fact that independent claim 33 does not require such switches notwithstanding, applicant respectfully submits that the Desai patent **does not** teach or suggest manually operable switches that control individual electrodes. To the contrary, the Desai patent merely teaches that the power supplying ablation unit 30 can be operated manually (without any reference to individual electrode control) and that the multiplexer connections between the ablation system 10 (i.e. the mapping unit 20, ablation unit 30 and pacing unit 40) and the catheter 70, auxiliary catheters 90 and surface electrodes 92 can be changed manually (again without any reference to individual electrode control). As such, the Desai patent would not have

suggested any modifications to the Eggers system that would have led a skilled artisan to the combination defined by independent claim 33.

4. The Teachings of the Fogarty Patent

The Fogarty patent, which was cited against dependent claim 40 for it purported teaching of a helical electrode, fails to remedy the above-identified deficiencies in the proposed Eggers/Desai combination with respect to independent claim 33.

5. Conclusion

As the Eggers, Desai and Fogarty patents fail to teach or suggest the combination of elements recited in independent claim 33, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 33, 35, 36 and 38-40 under 35 U.S.C. § 103 is improper and should be reversed.

E. CLAIMS 43 AND 44

In accordance with the separate patentability requirements of 37 C.F.R. § 1.192(c)(7), applicant respectfully submits claims 43 and 44 depend from independent claim 28 and, therefore, are patentably distinct from independent claim 33 and dependent claims 35, 36, 38, 39, 40, 45 and 46 (which depend from independent claim 33) for the same reasons as independent claim 28. In addition to being novel in view of claims 28, 30 and 32, applicant respectfully submits that claims 43 and 44 are also non-obvious over claims 28, 30 and 32 because the prior art does not suggest the use of the respective switch arrangements recited in claims 43 and 44 in combination with the inventions defined by claims 28, 30 and 32.

Turning to the rejection under 35 U.S.C. § 103, applicant respectfully submits that claims 43 and 44 are patentable over the proposed Eggers/Desai combination for at

least the same reasons as independent claim 28. Moreover, in addition to the elements recited in independent claim 28, the respective combinations of elements defined by claims 43 and 44 require that the "operator interface includes a plurality of manually operable switches respectively associated with the plurality of electrodes."⁵ One example of such an arrangement is illustrated in Figures 59 and 60, where seven toggles T_{E1-E7} /switches S_{E1-E7} are respectively associated with seven conductive regions E1 to E7. Applicant respectfully submits that the Eggers and Desai patents also fail to teach or suggest this aspect of the claimed combinations.

Referring to Figure 1, the Eggers power source 32 includes a single voltage control knob 34, a single temperature control knob 36, and what appears to be a single on-off power switch. **Each one** of the knob 34, the knob 36 and the on-off power switch are clearly associated with **all** of the electrodes 18 and, accordingly, are not associated with a respective electrode.

The Desai patent, which has apparently been cited to overcome this deficiency, fails to do so. The Desai patent discloses a catheter 70 with electrodes 111-115 that is connected to an ablation system 10 (i.e. a mapping unit 20, ablation unit 30 and pacing unit 40) by a multiplexer 80. The multiplexer 80 also connects auxiliary catheters 90 and surface electrodes 92 to the ablation system 10. The Desai patent does teach that the power supplying ablation unit 30 may be operated manually. It also teaches that the multiplexer 80 may be operated manually to switch the connections between ablation system 10 (i.e. the mapping unit 20, ablation unit 30 and pacing unit 40) and the catheter 70, auxiliary catheters 90 and surface electrodes 92. [Column 6, line 67 to column 7, line 6.] In contrast to the combinations defined by claims 43 and 44, however, the Desai patent does not even remotely suggest the use of an operator interface with "a plurality of manually operable switches **respectively associated** with the plurality of electrodes" on the catheter 70. There is no reference to individual electrode control at all. Thus, even when combined in the manner proposed in the Office Action, the Eggers and Desai patents fail to produce the claimed combination.

⁵ Claim 44 requires that the switches be "on-off" switches.

It is also noteworthy that the Eggers patent is directed to a system that can itself distinguish between atheromatous plaque and blood or a blood vessel wall so that the catheter can guide itself through the plaque. [Column 2, lines 22-35 and column 9, lines 18-22.] This is accomplished by **automatically** blocking power to those electrodes that come into contact with blood or a blood vessel wall. As such, there is simply no reason to add “a plurality of manually operable switches **respectively associated** with the plurality of electrodes” to the Eggers system other than the present hindsight attempt to reconstruct applicant invention.

As the cited references fail to teach or suggest the combination of elements recited in independent claim 43 and 44, applicant respectfully submits that the rejection of thereof under 35 U.S.C. § 103 is improper and should be reversed.

F. CLAIMS 45 AND 46

In accordance with the separate patentability requirements of 37 C.F.R. § 1.192(c)(7), applicant respectfully submits claims 45 and 46 depend from independent claim 33 and, therefore, are patentably distinct from independent claim 28 and dependent claims 30, 32, 43 and 44 (which depend from independent claim 28) for the same reasons as independent claim 33. In addition to being novel in view of claims 33, 35, 36 and 38-40, applicant respectfully submits that claims 45 and 46 are also non-obvious over claims 33, 35, 36 and 38-40 because the prior art does not suggest the use of the respective switch arrangements recited in claims 45 and 46 in combination with the inventions defined by claims 33, 35, 36 and 38-40.

Turning to the rejection under 35 U.S.C. § 103, applicant respectfully submits that claims 45 and 46 are patentable over the proposed Eggers/Desai combination for at least the same reasons as independent claim 33. Moreover, in addition to the elements recited in independent claim 33, the respective combinations of elements defined by claims 45 and 46 both require that the “operator interface includes a plurality of manually operable switches respectively associated with the plurality of electrodes” and

claim 46 further requires that the switches are on-off switches. Applicant respectfully submits that the Eggers and Desai patents also fail to teach or suggest this aspect of the claimed combinations.

Referring to Figure 1, the Eggers power source 32 includes a single voltage control knob 34, a single temperature control knob 36, and what appears to be a single on-off power switch. **Each one** of the knob 34, the knob 36 and the on-off power switch are clearly associated with **all** of the electrodes 18 and, accordingly, are not associated with a respective electrode.

The Desai patent, which has apparently been cited to overcome this deficiency, fails to do so. The Desai patent discloses a catheter 70 with electrodes 111-115 that is connected to an ablation system 10 (i.e. a mapping unit 20, ablation unit 30 and pacing unit 40) by a multiplexer 80. The multiplexer 80 also connects auxiliary catheters 90 and surface electrodes 92 to the ablation system 10. The Desai patent does teach that the power supplying ablation unit 30 may be operated manually. It also teaches that the multiplexer 80 may be operated manually to switch the connections between ablation system 10 (i.e. the mapping unit 20, ablation unit 30 and pacing unit 40) and the catheter 70, auxiliary catheters 90 and surface electrodes 92. [Column 6, line 67 to column 7, line 6.] In contrast to the combinations defined by claims 43 and 44, however, the Desai patent does not even remotely suggest the use of an operator interface with "a plurality of manually operable switches **respectively associated** with the plurality of electrodes" on the catheter 70. There is no reference to individual electrode control at all. Thus, even when combined in the manner proposed in the Office Action, the Eggers and Desai patents fail to produce the claimed combination.

It is also noteworthy that the Eggers patent is directed to a system that can itself distinguish between atheromatous plaque and a blood vessel wall so that the catheter can guide itself through the plaque. [Column 2, lines 22-35 and column 9, lines 18-22.] This is accomplished by **automatically** blocking power to those electrodes that come into contact with blood or a blood vessel wall. As such, there is simply no reason to add "a plurality of manually operable switches **respectively associated** with the plurality of

electrodes" to the Eggers system other than the present hindsight attempt to reconstruct applicant invention.

As the cited references fail to teach or suggest the combination of elements recited in independent claim 45 and 46, applicant respectfully submits that the rejection of thereof under 35 U.S.C. § 103 is improper and should be reversed.

IX. CONCLUDING REMARKS

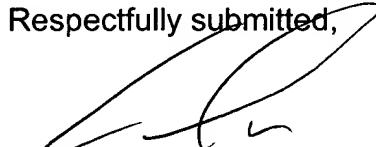
As applicant has shown above, the rejections of claims 28, 30, 32, 33, 35, 36, 38-40 and 43-46 are improper and should be reversed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

12/20/01
Date

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Respectfully submitted,



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